UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler

PLAINTIFFS' OBJECTION AND INCORPORATED MEMORANDUM OF LAW TO MODIFY SPECIAL MASTER REPORT AND ORDER NO. 46

Plaintiffs, by and through the Plaintiffs' Executive Committee, respectfully file this objection and incorporated memorandum of law to modify the Special Master Report (ECF 1614) and Order No. 46 (ECF 1615) on Plaintiffs' Motion for Leave to File Amended Master Complaints (ECF 1148) in two very discrete respects.

I. INTRODUCTION

Plaintiffs take no issue with the vast majority of the Special Master's thorough Report (ECF 1615) and Order No. 46 (ECF 1615). However, to protect against a waiver of any plaintiff's appellate rights in this MDL, Plaintiffs object to the Report and Order No. 46 on only two very discrete points, and request appropriate modification of that order.

First, Plaintiffs object to the Report and Order to the extent it denied Plaintiffs leave to amend all three Master Complaints to assert negligence claims against the Wholesaler and Retail Pharmacy Defendants. *See* ECF 1615 at ¶ 9. Second, Plaintiffs object to the Report and Order to the extent it denied Plaintiffs leave to amend the Master Complaints to assert implied warranty claims against Retail Pharmacy Defendants under various states' and territories' laws.

II. BACKGROUND

Plaintiffs filed a motion for leave to amend the master complaints on April 12, 2021. *See* ECF 1148. Once the motion was fully briefed, it was referred to the Special Master, who issued a report on October 7, 2021 (ECF 1614) and order on October 8, 2021 (ECF 1615). That order directed any party wishing to object to the Report or Order to do so within 21 days, or by October 29, 2021 (as confirmed at the October 27, 2021 case management conference).

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 53 permits the Court to appoint a Special Master "to address pretrial and posttrial matters." Fed. R. Civ. P. 53(a)(1)(C). The Court's appointment order of December 22, 2020 (ECF 692) in this matter authorizes the Special Master to "oversee the schedule for completion of discovery and all discovery disputes and motions….The authority of the Special Master hereunder shall be coextensive with that of a United States Magistrate Judge." *See* 12/22/20 Order (ECF 692). While an abuse of discretion generally applies to procedural or non-dispositive issues decided by a special master, *Valeant Pharms. Int'l Inc. v. AIG Ins. Co. of Canada*, No. 18-493, 2020 WL 7768405, at *4 (D.N.J. Dec. 30, 2020), a court should review de novo all objections to conclusions of law or findings of fact. *In re Johnson & Johnson Derivative Litig.*, Nos. 10-233, 11-4993, 11-2511, 2013 WL 6163858, at *3 (D.N.J. Nov. 25, 2013).

IV. ARGUMENT

The Court should modify the Special Master's Report and Order No. 46 to permit Plaintiffs leave to amend the Master Complaints to assert (i) negligence claims against Wholesaler and Retail Pharmacy Defendants, and (ii) implied warranty claims against Retail Pharmacy Defendants under various states' and territories' laws.

A. Negligence Claims Lie Against Wholesaler and Retail Pharmacy Defendants

This Court's MTD Opinion No. 5 dismissed without prejudice negligence claims against Wholesaler and Retail Pharmacy Defendants, in all three Master Complaints, because the Court sought additional clarity on the alleged negligent conduct of these defendants, as well as the duties that these defendants allegedly breached. *See* ECF 838 at 32.

Keeping this ruling in mind, the proposed amended complaints amplified the negligence allegations and theories against Wholesaler and Retail Pharmacy Defendants. As Plaintiffs pointed out in their briefing on the motion for leave to amend, wholesalers and retailers such as these Defendants owe common law duties to take appropriate steps to source generic drugs from their suppliers and ensure their suppliers did not sell adulterated, misbranded, or contaminated product. Pls.' Reply (ECF 1382) at 36. This includes, e.g., establishing or following adequate procedures to ensure that one's own suppliers take appropriate steps to ensure the drug products' safety. *Id.* More specifically, as alleged, Wholesaler Defendants had a duty to "develop verification methods to determine whether a product is valid, suspect or illegitimate product," *id.* at 38 (citing PELMC ¶ 4), to comply with cGMPS and GDPs, *id.* (citing PELMC ¶ 492), and to implement appropriate quality management systems to ensure unsafe or contaminated products do not enter the stream of commerce, *id.* (citing PELMC ¶ 493). None of these duties have anything to do with these defendants' repeated refrains that they did not have any "duty to test" the drugs the purchased and resold.

Further, Plaintiffs highlighted how wholesalers had a duty to "conduct risk assessment[s] to assess potential risks to the quality and integrity of pharmaceutical products." *Id.* (citing PELMC ¶¶ 491-503). In other words, Wholesaler Defendants could not leave their heads in the proverbial sand when sourcing valsartan from Manufacturer Defendants. Rather, they had

affirmative obligations to ensure that adequate steps were in place and, perhaps more importantly, that necessary quality assurance methods and cGMPs were followed by its own suppliers, the Manufacturer Defendants, to ensure that the product was not contaminated, adulterated or misbranded.

The same is true for Retail Pharmacy Defendants. *See id.* at 39-40. They, too, were obligated to take reasonable steps to ensure the product they sold was not contaminated, adulterated or misbranded. *Id.* (citing PELMC ¶¶ 461-464). They were obligated to comply with cGMP and GDP. *Id.* (citing PELMC ¶¶ 492-503). They also should have known of the nitrosamine contamination when their suppliers (Wholesalers and Manufacturer Defendants) did not provide adequate assurances of their own compliance with quality standards. *Id.*

Nevertheless, the Special Master denied leave to amend the Master Complaints to assert negligence against the Wholesaler and Retail Pharmacy Defendants because Plaintiffs' complaints (i) "cite no authority for the proposition that distributors of pharmaceuticals owe a duty to verify the integrity of a drug manufacturer's product," and no allegation that Wholesaler Defendants "knew of the nitrosamine contamination and failed to take reasonable steps in response to such knowledge." ECF 1614, at 35; *see also id.*at 37 (noting Plaintiffs did not allege that any Retail Pharmacy Defendant "had knowledge of the nitrosamine contamination").

Actual knowledge, however, is not a prerequisite to a negligence claim. Rather, the defining feature of a negligence claim is whether a defendant knew ***or should have known*** of an alleged condition of a product. *See, e.g.*, *Love v. Weecoo*, 774 Fed. Appx. 519, 521 (8th Cir. 2019) (applying Georgia law) (consumer plausibly asserted negligence claim against retailer, which sold consumer hoverboard that retailer had not manufactured itself, which allegedly had actual *or* constructive knowledge that hoverboard might catch on fire); *Gibbs v. Univ. Corr. Healthcare*,

No. 14-7138, 2016 WL 6595916, at *4 (D.N.J. Nov. 7, 2016) (applying New Jersey law) ("Negligence does not require actual knowledge."). Further, whether a defendant knew or should have known of the alleged condition of a product is a fact question. *See, e.g.*, *V.C. ex rel. Costello v. Target Corp.*, 435 F. Supp. 3d 415, 425-26 (D.N.J. 2020) (ruling on summary judgment whether evidence showed if retailer knew or should have known of dangerous condition). Any duty arises under familiar common law negligence principles, even if the complaints did not cite a singular source for a so-called "duty to verify the integrity of a drug manufacturer's product." The issue is whether Wholesaler and Retail Pharmacy Defendants exercised reasonable care in sourcing their drugs, and whether it was foreseeable that failure to do so would result in their selling contaminated drugs to consumers. *See, e.g.*, *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 211 (E.D.N.Y. 2014) (denying summary judgment for defendant on negligence claim against AmerisourceBergen, also a defendant here, for the distribution and sale of misbranded drug). Plaintiffs are entitled to have a jury decide the facts giving rise to such duties. *Id.* Indeed, these same defendants continued selling VCDs after the first recalls began in 2018. That they did nothing in the wake of the unprecedented notices about NDMA in VCDs, and simply sat back passively without going back to their suppliers to ensure that *other* VCDs that had yet to be recalled were NDMA-free (which, it turned out, they were not), is evidence enough from which a jury could find these defendants were negligent – especially so for purposes of amendment and at this pleadings-only stage, where inferences must be construed in Plaintiffs' favor.

Finally, a party should be permitted to amend a complaint with the benefit of discovery, especially on matters that are uniquely within a defendant's possession, such as facts about their own states of mind and what they actually knew or should have known. *See, e.g.*, *Wainwright v. City of Sharon*, No. 14-1212, 2016 WL 110015, at * 3-4 (W.D. Pa. Jan. 11, 2016) (collecting

cases). Here, Plaintiffs sought additional paper and deposition discovery from Wholesaler and Retail Pharmacy Defendants since December 2020. The Special Master did not allow the written discovery until June 10, 2021 (ECF 1306), did not approve deposition notices to these defendants until August 5, 2021 (ECF 1465), and all of the depositions of these defendants did not occur until just weeks ago. These defendants should not be rewarded for slow-playing discovery until after Plaintiffs filed their motion for leave to amend on April 12, 2021. *See, e.g.*, *Mason Tenders Dist. Council of Greater N.Y. v. Phase Constr. Servs., Inc.*, 318 F.R.D. 28, 37 (S.D.N.Y. 2016) (leave to amend should be granted where delayed discovery prevented party from discovering facts).

B. Additional Implied Warranty Claims Lie Against Retail Pharmacy Defendants

The Special Master denied leave to amend all three Master Complaints to assert implied warranty claims against Retail Pharmacy Defendants under the laws of 36 states, the District of Columbia, and Puerto Rico. *See* ECF 1614 at 25-26. The Special Master stated the basis for this was that Plaintiffs "failed to refute the accuracy" of Retail Pharmacy Defendants' chart of case law during the motion to dismiss briefing (*see* ECF 1614 at 25), and did not address these states the second time around in the motion for leave to amend briefing, *see id.* Plaintiffs respectfully submit that they *did* take issue with Retail Pharmacy Defendants' case law during the motion to dismiss stage. *See* Pls.' Opp'n (ECF 577) at 53-70. Plaintiffs certainly did address these 38 jurisdictions in the motion for leave briefing as well. *See* ECF 1382 at 31-35.

Both originally and on the motion for leave, Retail Pharmacy Defendants' argument about implied warranty improperly conflated that theory with the entirely separate theory of strict liability. Indeed, their very argument sub-heading was "Pharmacies are not subject to strict or warranty liability." *See, e.g.*, Retail Pharmacy Reply Br. (ECF 599) at 2; *id.* at 6 (arguing as to warranty liability the "problematic nature of imposing strict liability on pharmacies"). They also

insinuated that the fact-based "innocent seller" affirmative defense to strict liability precludes warranty liability as well. *Id.* Only later on in that same conflated section did they argue warranty theory separately, and there they argued they are "not merchants who warrant goods," *id.* at 6, even though the gravamen of this MDL is the *purchase* of a *good* merchanted by Retail Pharmacy Defendants.

Essentially, Retail Pharmacy Defendants conflated two theories – strict liability and implied warranty – and concocted a new legally unsupported liability shield to both by mingling the concepts. Further, as evidenced by defendants' own cases, the root of commingling strict liability and implied warranty theory is in product liability cases against manufacturers, not cases against resellers or retailers like Retail Pharmacy Defendants. *See, e.g.*, *Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 383 (D.N.J. 2019). In contrast, the laws of the various states and territories for which leave to amend was denied allow consumers to bring implied warranty claims against retailers. *See, e.g.*, *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 328 (D.N.J. 2014) (applying New Jersey law);[1] *see also, e.g.*, *Lee v. Kitchables Prods.*, No. 21-cv-1913, 2021 WL 3173253, at *4 (N.D. Cal. July 2021) (applying California law) (permitting plaintiff's implied warranty, negligence, and other claims to proceed against retailer, Amazon.com, which did not manufacture product); *Bieda v. CNH Industrial Am. LLC*, 518 F. Supp. 3d 863 (W.D. Pa. 2021) (applying Pennsylvania law) (denying summary judgment for defendants on implied warranty claim asserted by buyer against manufacturer *and* retailer); *Brodie v. Green Spot Foods, LLC*, 503 F. Supp. 3d 1, 8-9 (S.D.N.Y. 2020) (applying New York law) (finding consumer stated implied warranty, and

[1] "[Plaintiffs . . .] nevertheless ***may assert implied warranty claims against the retail sellers***, with whom they are in privity. All of the other plaintiffs live in states where privity is not required, and therefore may assert implied warranty claims against Whirlpool [the manufacturer], ***as well as the retailers*** from whom they bought their washers." *Dzielak*, 26 F. Supp. 3d at 328 (emphasis added).

negligence, claim against retailer for unsafe food sold but not manufactured by retailer); *Siedlik v. Stanley Work, Inc.*, 205 F. Supp. 2d 762, 764-65 (E.D. Mich. 2002) (applying Michigan law) (granting leave to amend to assert implied warranty claim against retailer).

They tried this again in the motion for leave to amend briefing. First, they claimed this Court found that pharmacies are not subject to strict liability "because they provide a service rather than sell a product, and therefore that they are not subject to breach of implied warranty claims, either. MTD Opinion 3 at 23-24." This Court held no such thing as to implied warranty. Similarly, the implied warranty counts in the Master Complaints do not state that the claims are based on a strict liability theory. *See, e.g.*, PELMC at ¶¶ 646-677; MMMC at ¶¶ 639-656; PIMC at ¶¶ 660-667.

Retail Pharmacy Defendants then compounded their misdirection by arguing on leave to amend that breach of implied warranty against pharmacies was "something that pleading amendments could not cure." ECF 1280 at 27. But this Court explicitly *granted* leave to amend all for the implied warranty claims, meaning that an insurmountable legal issue was not the root of dismissal without prejudice the first time. Retail Pharmacy Defendants then listed some cases from some but not all states and argued strict liability does not lie against pharmacies because they are innocent sellers, so therefore implied warranty claims must fail as well – which is not a legally valid argument.

Plaintiffs took this on at pages 33 to 35 of their reply brief in support of their motion for leave to amend. Plaintiffs noted (i) privity is not an obstacle because Retail Pharmacy Defendants are in direct seller relationships with Plaintiffs, and (ii) the so-called "innocent seller" statutes are fact-based affirmative defenses that should not be decided at the pleadings stage (for example, there are not facts yet on how "innocent" each Retail Pharmacy Defendant is, and there is no

indication as of now whether or to what extent the manufacturers will be financially willing or able to pay the damages that may be assessed in these cases). *See* ECF 1382 at 33-35. Plaintiffs incorporate by reference that argument and those cases here.

V. CONCLUSION

For the above-stated reasons, it is respectfully requested that the Court modify the Special Master's Report (ECF 1614) and Order No. 46 (ECF 1615) to allow leave to amend the Master Complaints to assert negligence claims against Wholesaler and Retail Pharmacy Defendants, and the implied warranty claims under the laws of the additional states and territories against Retail Pharmacy Defendants.

Dated: October 29, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of October, 2021, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system.

/s/ David J. Stanoch
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